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13. ABSTRACT *(Maximum 200 Words)*

Final report on a predoctoral training grant for a social psychology student and former cancer patient intending to work with cancer control and the psychosocial aspects of coping with cancer. Training was supervised and supported by Dr. Gary Morrow and the Behavioral Medicine Unit within the University of Rochester Cancer Center and led to the award of a doctorate in May, 2000 and the position of research assistant professor within the University of Rochester Cancer Center in July, 2000. The intervention to reduce chemotherapy-induced nausea and vomiting (NV) by increasing patients positive expectations through enhanced education was not successful. No significant differences were observed between the control (N=52) and treatment (N=45) groups in severity of nausea or occurrence of vomiting. Pilot data from a second study that was supported by this grant led to three years of additional funding from the DOD as a new idea award. The predoctoral training award was instrumental in my career development as a cancer researcher.

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Joseph Rowe 7-26-00

PI - Signature Date

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INTRODUCTION

Final report on a predoctoral training grant for a social psychology student and former cancer patient intending to work with cancer control and the psychosocial aspects of coping with cancer. The grant provided a stipend as well as research and training funds for three years of supervised training in psychosocial oncology research. This training opportunity combined with my graduate education, my perspective as a cancer survivor, and my experience as a cancer support group leader, was an essential element in my development as a productive researcher. I am well prepared to meet my personal and career goals of designing and testing interventions to improve the quality of life for cancer patients. The primary focus of my research has been and will be the role that expectations play in affecting cancer patient's response to treatment and development of side effects.

BODY

Training

Training was supervised and supported by Dr. Gary Morrow and the Behavioral Medicine Unit within the University of Rochester Cancer Center. Areas of training included data acquisition and analysis; interpretation of findings; preparation of research proposals and grants; and writing abstracts, papers, and book chapters. In addition, the training in psychosocial oncology research in the first year of the grant was augmented by a two-week internship at Stanford University in the techniques of supportive expressive group therapy used by Dr. David Spiegel in the running of his breast cancer support groups. I also visited the research team headed by Dr. Redd at the Mount Sinai Medical Center and attended the mini-convention on "psychology and cancer", which was part of the American Psychological Association's annual convention held in Boston in August, 1999. The mini-convention had presentations and seminars by many of the leading researchers in the field of psychology and cancer.

My predoctoral training included the design, implementation and analyses of a randomized controlled experiment examining the relationship between cancer patient expectations for experiencing chemotherapy-induced nausea and vomiting and subsequent symptom development. This experiment tested the hypothesis that an educational intervention for breast cancer patients prior to receiving their first chemotherapy treatment, that was designed to alleviate negative expectations about developing chemotherapy- related NV, would reduce subsequent development of treatment related NV.

Experiment Background

Although advances in antiemetic medications brought about by the introduction of the 5-HT3 receptor antagonist class of antiemetics (ondansetron, granisetron, tropisitron) have greatly reduced chemotherapy-related vomiting, this has not been the case with treatment-related nausea.[1] Together, the two symptoms remain among the most frequent side effects of cancer chemotherapy. Vomiting still occurs in approximately 25% of patients and nausea is reported by 78%. Roughly one-third of patients report nausea of

moderate or greater intensity.[1] Both symptoms are inherently unpleasant and their prominent role in reducing quality of life has been widely documented.[2-4]

Among patients, there is great variation in the frequency and severity of chemotherapy-induced nausea and vomiting (NV) that cannot be accounted for by pharmacologic properties of the chemotherapeutic agents or by known physiologic characteristics of patients. Patients' beliefs and expectations concerning NV development are postulated to account for some of the unexplained variance. These expectations, termed "response expectancies," are distinguished from both "stimulus expectancies" (i.e., anticipation of external consequences such as food, money, praise or punishment) and "intentions" (i.e., anticipation of voluntary response).[5]

Response expectancies have been predictive of symptom report in a number of studies from a variety of experimental perspectives including: recovery from wisdom tooth surgery;[6] postsurgical pain;[7] resumption of work, sexual and social activities after coronary artery bypass surgery;[8] return to work after a myocardial infarction;[9] and experimentally induced pain.[10-14]

Expectations as Predictors of Nausea and Vomiting

Researchers examining the relationship between patients' expectations and the development of treatment side effects have reported mixed results. Zook and Yasco[15] indirectly measured expectations for side effect development in 14 patients scheduled to be treated with chemotherapy for the first time by assessing their prior experience with a close friend or relative receiving chemotherapy. The investigators used a 5 item rating scale that ranged from 1 (extremely negative experience) to 5 (extremely positive experience) to categorize these patients' past experience with the person receiving chemotherapy. The responses these 14 soon-to-be-treated patients gave to this measure correlated significantly with their subsequent nausea development ($r = -.67$, $p > .01$).

Cassileth et al.[16] in a later study directly measured patients' pretreatment expectations for chemotherapy-related NV. They found no significant relationship between responses on their side effect expectancy questionnaire (SE-EXPECT) and later NV in 56 patients receiving chemotherapy for the first time. The questionnaire asked about 16 possible side effects on 5-point rating scales anchored by 1 (I am certain I will not have this) to 5 (I am certain I will have this).

Three later studies used a modified version of the SE-EXPECT scale in examining the relationship between expectations and chemotherapy-induced NV. Contrary to the findings by Cassileth et al., researchers led by Jacobsen[17] found that patients' pretreatment expectations were related to both the frequency and severity of posttreatment nausea in a group of 45 women with breast cancer receiving six weekly chemotherapy treatments. Likewise, Haut, Beckwith, Laurie, and Klatt[18] found a significant relationship between expectations and subsequent NV in 36 cancer patients with a variety of malignancies and treatment regimens beginning a first course of chemotherapy. However, the relationship between pretreatment expectations and posttreatment nausea development was not upheld in a later study of 65 patients by Andrykowski and Gregg.[19]

Rhodes and colleagues assessed expectations for NV in 329 patients prior to their first chemotherapy treatment with mixed findings.[20] Using Chi-squared analysis, a statistically significant relationship was found between expectations for nausea and

nausea development ($p > .05$) but not between expectations for vomiting and subsequent vomiting ($p > .1$). Researchers in another study[21] found a significant relationship between pretreatment expectations for nausea and anticipatory nausea measured prior to the sixth treatment in 59 breast cancer patients receiving chemotherapy. This finding remained significant even after controlling for both the severity and frequency of occurrence of posttreatment nausea ($p > .03$).

Roscoe et al.[22] reported on the relationship between response expectancies and symptom development in two companion studies. Expectations for nausea were assessed prior to first treatment in a homogeneous group of 31 subjects with ovarian cancer receiving platinum-containing chemotherapy as hospital inpatients (Study 1), and in 71 subjects with any of a variety of cancer diagnoses treated largely as outpatients (Study 2). Severity of nausea was assessed after patients' first and second treatments (Study 1) and after patients' first and third treatments (Study 2). Each study found a significant relationship between patients' expectations for nausea development measured prior to their first treatment and the mean post-chemotherapy nausea severity averaged across two treatments (all, $p < 0.05$). The relationships remained significant after controlling for emetic potential of the chemotherapeutic agents (Study 1: R^2 change = .153, $p = .03$; Study 2: R^2 change =.116, $p = .004$,).

These studies provide evidence that expectancy cognitions play a role in chemotherapy-induced side effect development. They join other psychological constructs, including conditioning[23,24] and anxiety[17,25] known to affect development of NV symptoms. Expectancies are closely related to these other two factors and may in fact be largely responsible for effects attributed to them. Negative expectancies are an instrumental factor in the development of anxiety.[26,27] Likewise, expectancy is thought to play a role in the generation of conditioning effects.[5,28,29] The magnitude of the effect of these psychological factors on NV development is amply demonstrated by the unfortunate fact that approximately 20% of chemotherapy patients experience NV prior to their treatments.[1] These psychological factors are also thought to contribute to the development and severity of posttreatment symptoms.[30,31]

How these response expectancies operate remains largely unknown. Kirsch[5] suggests that response expectancies account for the placebo effect and are self-confirming. While the biochemical and physiological mechanisms by which placebo effects influence treatment outcome remain largely unclear, it is clear that the effect is substantial and that expectations concerning treatment effectiveness are intimately associated with the process.[32,33] A selection of studies involving a manipulation of response expectancies for NV development are described below.

Seasickness was reduced by an expectancy manipulation in an experiment using what the authors termed a "verbal placebo".[34] Twenty-five naval cadets were randomly assigned prior to their maiden voyage to either a control condition of non-personalized information or to the experimental condition where each subject was told in confidence that he, based upon his previous psychological and physiological testing, was unlikely to experience as much seasickness as his fellow cadets. This experimental manipulation accounted for 31% of the variance in later reported seasickness ($p > .01$).

The effect caused by a manipulation of patients' expectations for NV development can also be seen in a study examining the efficacy of acupressure for control of these

symptoms. Ferrara-Love, Sekeres, and Bircher[35] conducted research on the efficacy of acupressure in reducing NV associated with outpatient surgery. Ninety participants were randomly assigned to receive either standard treatment, standard treatment plus an acupressure wristband, or standard treatment plus a sham acupressure wristband. The wrist bands were placed on the patients in the two treatment groups after surgery. The incidence of NV during the patients stay in the post anesthesiology care unit was significantly different between groups with 10% of the treatment group, 20% of the placebo group, and 50% of the control group reporting symptoms (overall, $p > .001$). While the true acupressure arm participants of this experiment trial did better than those in the sham acupressure arm, indicating the presence of a modest treatment effect, patients in both groups reported substantially lower rates of NV than reported by patients in the control group (all, $p > .01$)., thereby indicating the presence of a strong expectancy/placebo effect.

Williams and colleagues[36] reported success in reducing NV after major gynecologic operations by means of an expectancy manipulation involving intra-operative taped suggestions played while patients were under full anesthesia. Fifty-one patients were randomized to either the treatment condition of a tape containing positive statements concerning the ongoing surgery and how they would feel upon waking or to the control condition of a blank tape. The incidence of vomiting (32% vs.69%) and severity of NV (median of 1.5 vs. 5.0: range = 0-10) were significantly less for patients in the treatment condition compared to patients in the control condition (p's $< .05$).

The studies discussed provided a reasonable rationale for investigating a manipulation of patient expectation by dispelling misconceptions about and building confidence in the efficacy of their antiemetic drug regimen, and examining its potential in enhancing the antiemetic effects of drugs given for the control of chemotherapy-induced NV.

Technical Objectives:

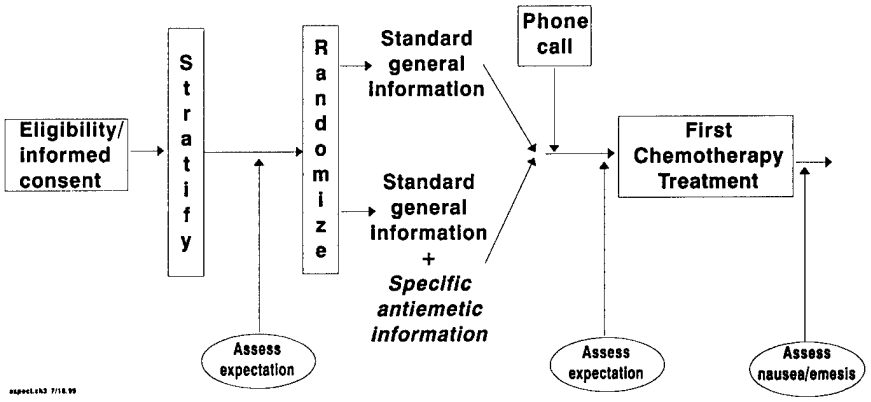
1. To assess the effectiveness of an educational manipulation to affect development of chemotherapy-induced NV as well as to affect patient's expectation for its occurrence.

2. To investigate the relationship between expectations for the development of chemotherapy-related NV and its actual occurrence.

Method

This was a randomized clinical trial of an education intervention for breast cancer patients prior to their first chemotherapy treatment specifically designed to provide an enhanced positive expectation for efficacy of their antiemetic medication.

Study Design



Measures

Expectation of Nausea and Other Side Effects. The measure of patient expectation for side effects was based on a questionnaire used previously by Andrykowski[19] (1992), Jacobsen et al.,[17] (1988), and Cassileth et al.,[16] (1985). Expectations of developing vomiting and nausea were assessed on separate five-point Likert-scales that were anchored at one end by "1" = "I am certain I will NOT have this," and at the other end by "5" = "I am certain I WILL have this". Patients who indicated a response of either "4" or "5" on this form were scored as expecting the symptom.

Nausea and Emesis were measured by a patient report diary developed by Burish[37] and Carey.[24] It has been used by several dozen investigators in studies over the past decade. Psychometric validity and reliability have been reported.[38,39]

Statistical Analyses and Assumptions

Outcome variables for this study are: severity of nausea and occurrence of vomiting during the first 24 hours after chemotherapy; severity of delayed nausea and occurrence of delayed vomiting during days 1-5 after chemotherapy; and change in expectations about nausea and vomiting following the intervention.

T-test for independent samples will be used to test for a difference between the control and intervention groups in acute and delayed nausea severity. Linear regression will be used to determine whether the intervention effect depends on age, sex, or race. In addition, regression will be used to explore the question of whether the intervention influences nausea and vomiting entirely through its effect on expectations. A linear regression model will be estimated using post-intervention expectation score as a covariate, but not including group assignment (control or intervention). Then group assignment will be added to the model. If it makes a significant contribution to the fit of the model beyond that provided by expectation, this will be evidence that the intervention acts in ways that are not fully captured by the expectation score.

Analyses similar to those described above using chi-squared tests and logistic regression will be used to test for a difference between the control and intervention groups in the proportions of patients who experience vomiting. An accrual of 72 patients was anticipated.

Procedures

Chemotherapy naive breast cancer patients scheduled to receive adriamycin treatments were stratified by age (under 50 vs. 50 or older) and randomized to one of two arms: Arm 1 = standard educational materials given to new patients; Arm 2 = specific intervention material as well as standard educational materials given to new patients.

The educational material given to all participants included two pamphlets produced by NCI and the ACS to inform patients about chemotherapy side effects and the general effectiveness of antiemetics. The intervention group received these same materials plus specific information designed to enhance expectations of efficacy by pointing out that ondansetron can control emesis in a majority of patients as well as be effective in the control of nausea. Patients were contacted by study personnel prior to their first chemotherapy appointment to insure that they have read the general information (both groups), read the specific information and answered a brief questionnaire to test whether they have read and understand the specific intervention information (intervention group), and completed the initial expectation measure (both groups). All patients completed the expectation measure both before and after the educational intervention.

All patients received a standardized dose of ondansetron (Ondansetron 20 mg IV infusion - over 15 min) and Dexamethasone (10 mg IV infusion - over 5-10 min). Patients were studied during the first course of chemotherapy and completed the measure of expectation prior to the intervention. Following the intervention they again filled out the expectation questionnaire (still prior to receiving chemotherapy). Patients completed the MANE and the 5-day diary of posttreatment side effects following treatment.

RESULTS

First Year Results (7-1-97 to 6-30-98)

This training and the research was primarily with my dissertation advisor Dr. Gary Morrow and the Behavioral Medicine Unit within the University of Rochester Cancer Center. Dr. Morrow is an experienced researcher in the area of behavioral and psychological interventions for cancer patients. As a member of Dr. Morrow's research team I was actively involved in the day-to-day activities of ongoing psychosocial and physiologic studies. With his assistance I analyzed the data from four completed research studies and managed the databases and data input from two others. We collaborated on several publications including three journal articles, two chapters, and three abstracts during the 12 month period. Four additional articles were submitted for publication. I have also took part in the writing of two research protocols and two grant proposals generated by our office and critically examined three grant proposals and two articles that Dr. Morrow was asked to review.

In June, 1997 I spent two weeks at Stanford University in the Spiegel Laboratory. I was able to observe Dr. Spiegel work firsthand with a support group and had several

conversations with him concerning aspects of psychosocial interventions and research. Dr. Spiegel generously allowed me to analyze data from two of his studies.

My proposed randomized controlled experiment examining the relationship between breast cancer patient expectations for experiencing chemotherapy-induced nausea and vomiting and subsequent symptom development underwent substantial delay and modification in order to accommodate an unexpected problem. The study, which was to serve as my dissertation study, was approved by my advisor, the hospital institutional review board and the grant reviewers from your institution. Unfortunately, and unexpectedly, the proposal was rejected by the chairman of my social psychology department as unsuitable for a dissertation because it was unlikely to yield new or interesting information. Lengthy negations lead to a two-prong solution to the problem this presented.

First, in order to meet the obligations of my predoctoral training grant, I assumed responsibilities for data management, analyses and report writing for a URCCCCOP protocol that also examined the relationship between patient expectations and subsequent symptom development. This is a study I wrote with Dr. Morrow concurrently with writing my dissertation and grant proposal. The URCCCCOP study, which is larger in both scope and size than my grant proposal study, includes all the essential elements (including measures and the information based expectancy manipulation) of my grant study. The experimental results described in this present report are from URCCCCOP study. This study began accruing patients in January 1998.

Second, my previously proposed dissertation study was modified to include a stronger expectancy manipulation and an additional control group. The modified proposal still entailed conducting a randomized controlled experiment examining the relationship between cancer patient expectations for experiencing chemotherapy-induced nausea and vomiting and subsequent symptom development. The expectancy manipulation involved use of an acupressure wrist band and information that it has been shown to be effective in reducing NV. An additional control group (using a sham acupressure treatment) was added to the study to control for actual acupressure effects. The revised version of my dissertation proposal received approval by the hospital institutional review board. The study began accrual in early 1998.

Second Year Results (7-1-98 to 6-30-99)

Both the URCCCCOP protocol and my dissertation study accrued patients without incident. Preliminary analyses from the dissertation study provided pilot data for an idea grant proposal I submitted to Department to the Defense in June, 1999.

I continued to work closely with Dr. Morrow and was involved in all aspects of the research taking place in our office including data analyses, report writing, and manuscript reviews. A research protocol on acupressure that I authored was approved by the NCI and will open for patient accrual later this year. One article that I co- was accepted in the journal *Cancer.*

In June, 1999 I requested permission to change one of the short internships specified in my pre-doctoral training. I had originally proposed spending two weeks at Memorial Sloan-Kettering Cancer Center, under the guidance of Dr. William Redd, to learn more about the role of conditioning in the development and prevention of

chemotherapy side effects. Since the time of my application, Dr. Redd had accepted employment at the Mount Sinai Medical Center, where he headed a research program examining the effectiveness of interventions designed to relieve family members' stress by including them in patient care. My request to change my planned two-week visit at Memorial Sloan-Kettering Cancer Center to a shorter one at the Mount Sinai Medical Center was granted. I also received permission to attend the mini-convention on "psychology and cancer" sponsored by the American Psychological Association held in Boston in August, 1999.

Third Year Results (7-1-99 to 6-30-00)

My modified dissertation study using an acupressure wrist band to generate an expectancy manipulation was completed and accrued 30 breast cancer patients. I presented and successfully defended this dissertation in April, 2000 and received my doctorate in May, 2000. The DOD Idea grant proposal based upon this study that I submitted in June, 1999 was funded and accrual has recently begun.

I continued to work closely with Dr. Morrow and continued to be involved in all aspects of the research taking place in our office. We have had several articles accepted for publication during the year and I was lead author on two of these.

As planned, I visited the research team headed by Dr. Redd at the Mount Sinai Medical Center in April of this year and attended the mini-convention on "psychology and cancer" held in Boston in August, 1999. The mini-convention had presentations and seminars by many of the leading researchers in the field of psychology and cancer.

Study Results

These results are based upon analyses of 100 breast cancer patients from the URCCCCOP protocol on expectations. Ninety-seven of these patients provided evaluable data. The average patient was just over 53 years of age (range: 28 - 79) and all but 13 of the women were Caucasian. All patients received chemotherapy containing doxorubicin and a standardized dose of ondansetron as an antiemetic.

Calculation of Acute and Delayed NV Variables

The patient five-day diary (with nausea severity recorded four times a day on a 7-point scale) was used to calculate nausea severity for each patient for each treatment. Responses from the morning and afternoon of the day of treatment were ignored because some patients did not complete their treatments until late afternoon. Acute nausea (the mean of the four responses starting from evening of the day of treatment through afternoon of the next day) and delayed nausea (the mean of the 14 responses starting from evening of the day following treatment through night, four days later) variables were created. Variables indicating the presence or absence of acute and delayed vomiting were also created from this record. The two measures of nausea and the two measures of vomiting were used as outcome measures throughout these analyses.

Statistical Analyses

Most patients (85%) reported some nausea following treatment, with acute nausea severity averaging 2.3 (range = 1 - 7) and delayed nausea severity averaging 1.9 (range =

1 – 4.7). Just over a quarter of the patients (25%) reported vomiting following their treatment, with 18% of patients experiencing acute emesis and 16% reporting delayed emesis.

Group Differences: No significant differences were observed between groups in either acute nausea severity ($mean_{control}$ 2.2 *v* $mean_{intervention}$ 2.3, t (96) = -.17, $p = 0.86$) nor delayed nausea severity ($mean_{control}$ 1.8 *v* $mean_{intervention}$ 2.0, t (96) = -1.25, $p = 0.22$). Likewise, no significant differences were observed between groups in the occurrence of acute vomiting, χ^2 (1) = .02, $p = .41$, nor delayed vomiting, χ^2 (1) = .02, $p = .41$. Group assignment was not related to changes that did occur in nausea expectancies from pre to post intervention (calculated by subtracting the later measure from the earlier measure) ($mean_{control}$ 0.21 *v* $mean_{intervention}$ 0.36, t (95) = -.64, $p = 0.52$) or for vomiting expectancies ($mean_{control}$ 0.46 *v* $mean_{intervention}$ 0.20, t (95) = 1.1, $p = 0.27$).

Expectations and Nausea: Of the 97 patients, 32% (31) expected to experience treatment-induced nausea, measured post intervention but prior to treatment, and 66 reported they were either unsure about what would occur or that they did not expect any nausea. Expectations of nausea were significantly correlated with age in this sample, with younger age (Spearman's rho = -.23, $p = .03$) being associated with greater expectations for nausea. Expectations of nausea, however, were not significantly correlated with either acute nausea severity ($mean_{expect}$ 2.3 *v* $mean_{not\ expect}$ 2.2, t (96) = -.33, $p = 0.74$) nor delayed nausea severity ($mean_{expect}$ 2.0 *v* $mean_{not\ expect}$ 1.9, t (96) = -.37, $p = 0.71$). No significant differences were observed between groups in the occurrence of acute vomiting, χ^2 (1) = .02, $p = .41$, nor delayed vomiting, χ^2 (1) = .02, $p = .41$

Expectations and Vomiting: Twenty (21%) of the 97 patients expected to experience treatment-induced vomiting, and 77 (79%) reported they were either unsure about what would occur or that they did not expect to vomit. Expectations of vomiting were not significantly correlated with occurrence of acute vomiting, χ^2 (1) = .01, $p = .75$, nor delayed vomiting, χ^2 (1) = .004, $p > 0.95$.

Discussion and Conclusion

These data indicate that the experimental intervention using an educational manipulation to affect mitigate patient's expectation for the development of chemotherapy-induced NV and thereby reduce its subsequent occurrence was not successful. Neither expectations for the development of NV nor actual NV were reduced in the experimental group compared to the control group. Unfortunately, because the experimental manipulation failed to reduce NV expectancies, it cannot be determined from this data whether or not NV can indeed be reduced through an expectancy manipulation. An additional study using a more effective expectancy manipulation will be necessary to answer that question.

It is not clear why the expectancy manipulation failed. It is possible that the intervention material did not convey information that was new and relevant to patients. This view is supported by the fact that fewer than half of the patients expected NV, suggesting that most patients already believed that they would not experience NV.

The secondary objective of this study was to investigate the relationship between expectations for the development of chemotherapy-related NV and its actual occurrence. These data do not support the existence of a relationship between these two variables.

This is in variance with some[15,17,18,22] but not all[16,19] prior publications on this relationship. Based upon a reading of the mixed literature, it seems probable that a relationship between expectations and NV symptom development exists but that it is a weak one, thus accounting for why some researchers examining this relationship report positive findings while other do not. Additional research and a meta-analysis of existing research are recommended.

KEY RESEARCH ACCOMPLISHMENTS

- Completed dissertation study
- Wrote and became co-investigator on NCI funded study examining acupressure for chemotherapy-induced NV relief

REPORTABLE OUTCOMES

- Received doctorate
- Received additional three years funding to continue dissertation research from DOD
- Poster presented at DOD conference in Atlanta, 2000

CONCLUSIONS

I am made excellent use of the opportunity afforded by the grant and by Dr. Morrow and look forward to a productive career in psychosocial oncology research.

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